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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
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Stephen Griffin

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EXAMINER

FOREMAN, JONATHAN M

ART UNIT

PAPER NUMBER

3736

MAIL DATE

DELIVERY MODE

07/21/2009

PAPER

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary	Application No. 10/025,668	Applicant(s) GRIFFIN ET AL.	
	Examiner JONATHAN ML FOREMAN	Art Unit 3736	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 20 March 2009.
- 2a) ☒ This action is **FINAL**. 2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1,5-16,20,24-36,38 and 45 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☒ Claim(s) 1,5-16 and 36 is/are allowed.
- 6) ☒ Claim(s) 20,24-35,38 and 45 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
 2. ☐ Certified copies of the priority documents have been received in Application No. _____.
 3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|--|---|
| 1) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413) |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | Paper No(s)/Mail Date. _____ |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO/SB/08) | 5) <input type="checkbox"/> Notice of Informal Patent Application |
| Paper No(s)/Mail Date _____ | 6) <input type="checkbox"/> Other: _____ |

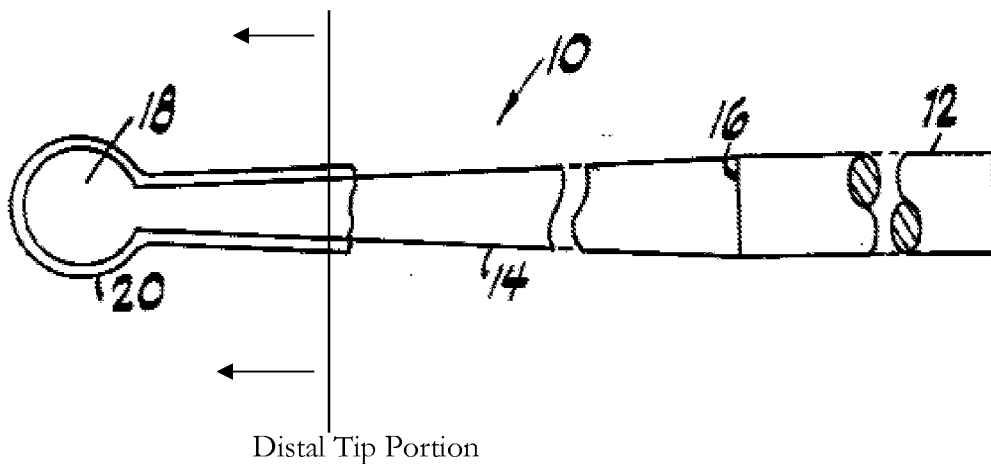
DETAILED ACTION***Claim Rejections - 35 USC § 103***

1. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

2. Claims 20, 24, 25, 38 and 45 are rejected under 35 U.S.C. 103(a) as being unpatentable over U.S. Patent No. 5,368,049 to Raman et al. in view of U.S. Patent No. 6,024,764 to Schroepel.

In regard to claims 20, 24, 25 and 38, Raman et al. disclose an elongate core wire comprising a distal tip portion (See Below) formed of a super elastic nickel titanium alloy (Col. 4, lines 49 – 51; Col. 5, lines 15 – 16) having an elastic limit.



Raman et al. disclose a formable cladding (20) surrounding the entire distal tip portion such that a substantial portion of the cladding is in continuous contact with the core wire, the cladding is more stiff than the distal tip portion of the guidewire which it surrounds to allow a physician to impart a shape to the distal tip (Col. 5, lines 6 – 14). The portion of the core wire surrounded by the

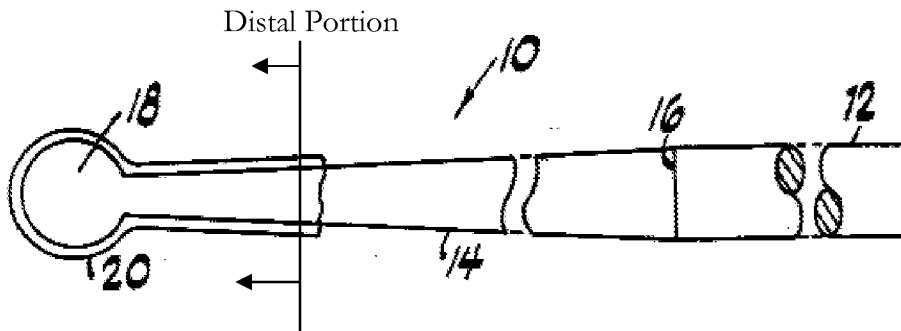
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cladding is bent into a curved shape and maintains the curved shape (Col. 4, lines 66 – 68) by overcoming biasing forces imposed by the elongate core wire which tend to straighten the core wire. However, Raman et al. fail to disclose the cladding being a shape memory polymer jacket, wherein the shape memory polymer is one from a subset of polymers which are characterized by their responsiveness to heating at or above a glass transition temperature of the shape memory polymer in order to independently transform the shape memory polymer between a first and second shape. Schroepel discloses a guiding element for positioning within a patients body (Col. 5, lines 12 – 15) including a polymer jacket being a shape memory polymer more stiff than the portion of the core wire which it surrounds (Col. 5, lines 41 – 57); wherein the shape memory polymer is one from a subset of polymers which are characterized by their responsiveness to heating at or above a glass transition temperature of the shape memory polymer in order to independently transform the shape memory polymer between a first and second shape, wherein the glass transition temperature is greater than the body temperature of the patient such that a curved shape imparted on the guiding element is maintained (Col. 4, lines 51 – 65). Schroepel discloses that any number of different types of tubular devices can include such a jacket (Col. 3, lines 53 – 57). It would have been obvious to one having ordinary skill in the art to modify the cladding as disclosed by Raman et al. to include a shape memory polymer jacket as taught by Schroepel so the device can be shaped by a surgeon into a shape and subsequently reshaped if desired to allow for introduction into the patient's anatomy (Col. 5, lines 50 – 60) without having to worry about fractures forming in the cladding from repeated use.

In regard to claim 45, Raman et al. disclose an elongate core wire comprising a proximal portion and a distal portion formed of a super elastic nickel titanium alloy (Col. 4, lines 49 – 51; Col.

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5, lines 15 – 16) having an elastic limit and a resiliency to being substantially straight (Col. 3, lines 1 – 8).



Raman et al. disclose a formable cladding (20) attached to and surrounding at least the distal portion of the core wire formed of a super elastic nickel titanium alloy, the cladding is in continuous contact with the core wire throughout a majority of the length of the cladding, the cladding is more stiff than the portion of the guidewire which it surrounds to allow a physician to impart a shape to the distal tip (Col. 5, lines 6 – 14). The portion of the core wire surrounded by the cladding includes a tapered portion and is bent into a curved shape and maintains the curved shape (Col. 4, lines 66 – 68) by overcoming biasing forces imposed by the elongate core wire which tend to straighten the core wire. However, Raman et al. fail to disclose the cladding being a shape memory polymer jacket, wherein the shape memory polymer is one from a subset of polymers which are characterized by their responsiveness to heating at or above a glass transition temperature of the shape memory polymer in order to independently transform the shape memory polymer between a first and second shape. Schroepel discloses a guiding element for positioning within a patients body (Col. 5, lines 12 – 15) including a polymer jacket being a shape memory polymer more stiff than the portion of the core wire which it surrounds (Col. 5, lines 41 – 57); wherein the shape memory polymer is one from a subset of polymers which are characterized by their responsiveness to heating at or above a

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glass transition temperature of the shape memory polymer in order to independently transform the shape memory polymer between a first and second shape, wherein the glass transition temperature is greater than the body temperature of the patient such that a curved shape imparted on the guiding element is maintained (Col. 4, lines 51 – 65). Schroepel discloses that any number of different types of tubular devices can include such a jacket (Col. 3, lines 53 – 57). It would have been obvious to one having ordinary skill in the art to modify the cladding as disclosed by Raman et al. to include a shape memory polymer jacket as taught by Schroepel so the device can be shaped by a surgeon into a shape and subsequently reshaped if desired to allow for introduction into the patient's anatomy (Col. 5, lines 50 – 60) without having to worry about fractures forming in the cladding from repeated use.

3. Claims 26 - 35 are rejected under 35 U.S.C. 103(a) as being unpatentable over U.S. Patent No. 5,368,049 to Raman et al. in view of U.S. Patent No. 6,024,764 to Schroepel as applied to claims 1 and 20 above, and further in view of U.S. Patent No. 6,485,458 to Takahashi.

In reference to claims 26 - 35, Raman et al. in view of Schroepel disclose a shape memory polymer surrounding a portion of the core wire being polynorborene, polyurethane and similar materials (Col. 7, lines 46 – 50), but fails to disclose the polymer being polcaprolactone, polymethylmethacrylate, PLLA, PLLA OGA, PL/D LA, PMMA, polyethylene, polyisoprene, styrene-butadiene or photocrosslinkable polymer. However, Takahashi discloses a shape memory polymer surrounding a core wire wherein the polymer consists of poluorbornen, styrene-butadiene, polyisoprene, polyester, polyolefin, acrylic and styrene-acrylic (Col. 5, lines 56 – 67). Takahashi teaches that other shape-memory materials can be used in addition to those disclosed. It would have been obvious to one having ordinary skill in the art at the time the invention was made use any shape memory polymer as taught by Takahashi in the device as disclosed by Raman et al. in view of

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Schroeppel in that Takahashi teaches that shape memory polymers are interchangeable.

Additionally, the selection of a known material based upon its suitability for the intended use is a design consideration within the skill of the art. *In re Leshin*, 227 F.2d 197, 125 USPQ 416 (CCPA 1960). In the present case, replacing the shape memory polymer as disclosed by Raman et al. in view of Schroepel with any other shape memory polymer is a design consideration within the skill of the art.

Response to Arguments

4. Applicant's arguments filed 3/20/09 have been fully considered but they are not persuasive. Applicant asserts that a *prima facie* case of obviousness has not been established. However, the Examiner disagrees. Applicant points out that Schroepel is silent regarding the material of the implantable tubular device, and points to a disclosure of a plurality of barbs 24 on the tubular sleeve to penetrate into an exterior surface of an implantable tubular device. Applicant suggests that this negates any suggestion that Schroepel teaches that the implantable tubular device may be metallic. However, Schroepel also discloses the use of biocompatible adhesives to secure the sleeve to an implantable tubular member (Col. 4, lines 25 - 28). Schroepel discloses that any number of different types of tubular devices, including shunts, can include a shape memory sleeve (Col. 5, lines 5 - 12). It is noted that shunts are commonly formed of metallic materials (See U.S. Patent Application Publication No. 2002/0165478 to Gharib et al. [0029]). The Examiner maintains that it would have been obvious to one having ordinary skill in the art to modify the cladding as disclosed by Raman et al. to include a shape memory polymer jacket as taught by Schroepel so the device can be shaped by a surgeon into a shape and subsequently reshaped if desired to allow for introduction into the patient's anatomy (Col. 5, lines 50 - 60) without having to worry about fractures forming in the cladding from repeated use.

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Allowable Subject Matter

5. Claims 1, 5 – 16 and 36 are allowed.

Conclusion

6. **THIS ACTION IS MADE FINAL.** Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the mailing date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to JONATHAN ML FOREMAN whose telephone number is (571)272-4724. The examiner can normally be reached on Monday - Friday 8:00 am - 4:30 pm.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Max Hindenburg can be reached on (571)272-4726. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

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Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

/J. M. F./
Examiner, Art Unit 3736

/Max Hindenburg/
Supervisory Patent Examiner, Art Unit 3736